BS

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,726	12/21/2001	Wen-Hwa Lee	17726A-000420US	4418

20350 7590 12/03/2004

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,726	LEE ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The specification has been amended as requested in the response filed 7-19-04.

Priority

The claims have support in claims 41-47 as originally filed, and pg 43, 1st ¶. Claims 41-47 as originally filed can also be found in 07/265,829 and suppression of the neoplastic phenotype is found on pg 53, line 1, of '829.

Claim Rejections - 35 USC § 102

1. Claims 49-56 remain rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for reasons of record.

Applicants (Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee) claim a method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype. Wen-Hwa Lee and Phang-Lang Chen (US Patent 5,532,220) invented a method of treating mammalian cancer cells lacking endogenous wild-type p53 protein by introducing a wild-type p53 gene into the cells, thereby suppressing the cells' neoplastic phenotype. p53 is a portion of the RB gene; therefore, using RB encompasses using p53. The present claims encompass the claims of '220. (It is readily apparent that the previous office action reversed the scope of the present claims when saying the claims of '220 encompass the present claims). Wen-Hwa Lee and Phang-Lang Chen described the function of the RB protein and introducing a wild-type copy of RB into retinoblastoma cells, which suppressed their tumorigenic properties

(col. 5, lines 7-10). Wen-Hwa Lee and Phang-Lang Chen state RB and p53 had equivalent functions (col. 5, line 26-28). Therefore, Wen-Hwa Lee and Phang-Lang Chen taught a copy of the whole RB gene could be used to suppress a tumor phenotype as claimed in the instant application.

Applicants argue the claims of '220 require treating cells lacking endogenous wild-type p53 using a wild-type p53 gene while the instant invention requires treating cells lacking endogenous wild-type RB using a wild-type RB gene. Therefore, applicants conclude that the methods are directed toward treating different classes of cancer cells. Applicants' argument is not persuasive. The methods are directed toward treating different scopes of cancer cells. The classes of cancer cells being treated related because p53 is a fragment of the RB gene. Thus, treating cells lacking endogenous p53 ('220) is within the scope of treating cells lacking endogenous wild-type RB (presently claimed) because p53 is part of the RB protein. Wen-Hwa Lee and Phang-Lang Chen taught a copy of wild-type of RB could be used to suppress the neoplastic phenotype (col. 5, lines 7-10). Thus, Wen-Hwa Lee and Phang-Lang Chen taught the entire RB gene could also be used to suppress the neoplastic phenotype as claimed in the instant application.

2. Claims 49-56 remain rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for reasons of record.

Applicants (Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee) claim a method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic

phenotype. The inventive entity in the instant application is incorrect because Dr. Theodore Friedmann and Dr. Jiing-Kuan Yee designed the vector encoding RB for treating cancer cells as claimed. The design of a vector for gene therapy was known at the time of filing to be essential to obtain the desired effect. Dr. Friedmann and Dr. Yee determined the elements of the vector required to obtain adequate and stable expression of RB (see declarations by Dr. Theodore Friedmann and Dr. Jiing-Kuan Yee filed 12-21-01). Therefore, Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee did not invent the claimed subject matter alone.

The attempt to overcome the rejection by providing a petition to change inventorship under Rule 47 is not persuasive because the petition was dismissed. A separate copy of the dismissal was sent 11-24-04.

Double Patenting

3. Claims 49-56 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,532,220 for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treating mammalian cancer cells lacking endogenous wild-type p53 protein by introducing a wild-type p53 gene into the cells, thereby suppressing the cells' neoplastic phenotype in '220 is a species of the method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype as claimed in the instant application. Claims 51-56 are equivalent to claims 3-6 of '220.

Applicants argue the claims of '220 require treating cells lacking endogenous wild-type p53 using a wild-type p53 gene while the instant invention requires treating cells lacking endogenous wild-type RB using a wild-type RB gene. Therefore, applicants conclude that the methods are directed toward treating different classes of cancer cells. Applicants' argument is not persuasive. The methods are directed toward treating different scopes of cancer cells. The classes of cancer cells being treated are related because p53 is a fragment of the RB protein. Thus, treating cells lacking endogenous p53 ('220) is within the scope of treating cells lacking endogenous wild-type RB (presently claimed) because p53 is a fragment of the RB protein. Wen-Hwa Lee and Phang-Lang Chen taught a copy of wild-type of RB could be used to suppress the neoplastic phenotype (col. 5, lines 7-10). Thus, Wen-Hwa Lee and Phang-Lang Chen taught the entire RB gene could also be used to suppress the neoplastic phenotype as claimed in the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER